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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,660	05/09/2006	Philip C. Dell'orco	PU60518	4972
20462	7590	11/20/2007	EXAMINER	
SMITHKLINE BEECHAM CORPORATION			AULAKH, CHARANJIT	
CORPORATE INTELLECTUAL PROPERTY-US, UW2220			ART UNIT	PAPER NUMBER
P. O. BOX 1539			1625	
KING OF PRUSSIA, PA 19406-0939			NOTIFICATION DATE	DELIVERY MODE
			11/20/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[US\\_cipkop@gsk.com](mailto:US_cipkop@gsk.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/578,660	DELL'ORCO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Charanjit S. Aulakh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 and 9-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 and 9-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.                                     |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/9/06, 11/28/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____.                         |

**DETAILED ACTION**

1. According to paper filed on May 9, 2006, the applicants have canceled claims 7, 8 and 26-28 and furthermore, have amended claims 5, 6, 9-11, 18, 20-23 and 25.
2. Claims 1-6 and 9-25 are now pending in the application.

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9, 10 and 18-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Boehm ( U.S. Patent 5,004,758, cited on applicant's form 1449 ).  
Boehm discloses water soluble camptothecin analogs useful for inhibiting the growth of animal tumors. In table 2, Boehm discloses instant camptothecin analog (topotecan) and in tables 3-10, Boehm teaches anticancer activity of topotecan in various animal tumor models. The pharmaceutical composition comprising hydrate of topotecan monohydrochloride ( see claims 17-25 and specifically claim 23 ) and method of inhibiting the growth tumor cells using hydrate of topotecan monohydrochloride ( see claims 26-34 and specifically claim 32 ) clearly anticipates the instant claims. It is of note that pentahydrate form of topotecan will not be maintained in pharmaceutical composition as well as following its in vivo administration. The pharmacological utility of topotecan is due to compound itself and does not reside in the hydrate form. Also, amelioration of symptoms associated with cancer will be inherent following administration of topotecan.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-6 and 11-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boehm ( U.S. Patent 5,004,758, cited on applicant's form 1449 ) in view of Pothukuchi ( WO 03/027118, cited on applicant's form 1449 ).

Boehm discloses water soluble camptothecin analogs of formula (I) or a pharmaceutically acceptable salt or hydrate thereof ( see column 4, line 40 to col. 5, line

5. In tables 2 and 10, Boehm discloses instant 1S camptothecin analog (topotecan).

Boehm meets all the limitations of instant claims except that it does not teach preparing specifically pentahydrate form of topotecan. However, Pothukuchi discloses preparing various polymorphs including hydrate forms of pharmaceutically acceptable salts of camptothecin derivatives and further teaches determination of these polymorphic forms by various methods such as DSC, powder X-ray diffraction, IR spectroscopy, solid

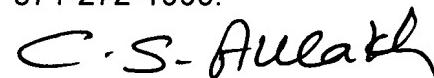
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probe NMR spectroscopy etc. ( see page 9, lines 3-13 ). Therefore, it would have been obvious to one skilled in the art to prepare the instant polymorphic pentahydrate form of topotecan monohydrochloride since preparation of polymorphic forms of a compound is within the routine skill of an artesian.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Charanjit S. Aulakh  
Primary Examiner  
Art Unit 1625